



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/722,867	11/27/2000	Maria Grazia Pau	4626US	4248
24247	7590	11/02/2006	EXAMINER	
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			HILL, MYRON G	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

TH

Office Action Summary

Application No.

09/722,867

Applicant(s)

PAU ET AL.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36,38-40,42-45 and 50-52 is/are pending in the application.
- 4a) Of the above claim(s) 36,38,39,45 and 52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40,42-44,50 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In view of the Appeal Brief filed on 18 July 2006, PROSECUTION IS HEREBY REOPENED. A *new ground of rejection* is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

A handwritten signature in black ink, appearing to read "Bruce Campell". The signature is written in a cursive, flowing style.

Bruce Campell.

Claims 40, 42-44 and 46-51 are under consideration.

Rejections Withdrawn

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 40, 42-44, 50, and 51 were rejected under 35 U.S.C. 103(a) as being unpatentable over and Merton *et al.* in view of Paul RW *et al.* (Paul).

The rejection is presented again below with an added reference.

New Rejections

Claim Rejections - 35 USC § 103

Claims 40, 42-44, 50, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over and Merton *et al.* and Paul *et al.* in view of Trudel *et al.*

The claims are drawn to a method of concentrating cell cleared influenza virus containing supernatant under low shear conditions using ultrafiltration. The dependent claims add cutoff values for the ultrafiltration.

Applicant argues that there is no motivation to combine, that the hollow fiber ultrafiltration method of Paul is not generally applicable because the teachings of Paul are limited to retroviruses and do not include influenza viruses, that there is no expectation of success, and that the references do not teach each and every element of claims 43 and 51.

Applicant's arguments have been fully considered and not found persuasive.

Merton *et al.* and Paul *et al.* have already been discussed.

Trudel *et al.* teach that hollow fiber ultrafiltration is one of the most effective ways of achieving rapid viral concentration without loss of activity and that the method has

Art Unit: 1648

been used on a number of viruses and that pore size is a consideration that effects flow rates (page 2, first paragraph).

One of ordinary skill in the art at the time of invention would be motivated to purify large scale volumes of influenza as needed by Merton *et al.* One of ordinary skill in the art at the time of invention would have the expectation of success of using hollow fiber ultrafiltration knowing that it has been used to purify viruses and that it is taught to be one of the most rapid ways of concentrating virus without losing infectivity as taught by Trudel *et al.* One of ordinary skill in the art would be motivated to use methods that are effective in concentrating large volumes of virus without loss of infectivity. It would be routine experimentation for one of ordinary skill in the art to examine different pore cutoff sizes knowing that size effects flow rates as taught by Trudel *et al.*

Thus, it would be *prima facie* obvious to purify the influenza virus with hollow fiber ultrafiltration with the expectation of success knowing that it is one of the most effective ways of achieving rapid viral concentration without loss of activity.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

Art Unit: 1648

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Myron G. Hill
Patent Examiner
20 February 2006



BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600